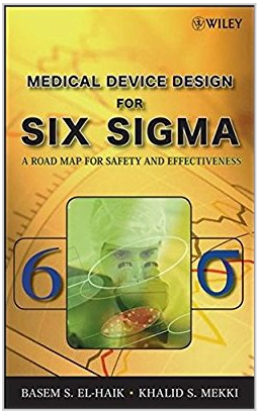

Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness

By Basem El-Haik, Khalid S. Mekki

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The first comprehensive guide to the integration of Design for Six Sigma principles in the medical devices development cycle

Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness presents the complete body of knowledge for Design for Six Sigma (DFSS), as outlined by American Society for Quality, and details how to integrate appropriate design methodologies up front in the design process. DFSS helps companies shorten lead times, cut development and manufacturing costs, lower total life-cycle cost, and improve the quality of the medical devices. Comprehensive and complete with real-world examples, this guide:

- Integrates concept and design methods such as Pugh Controlled Convergence approach, QFD methodology, parameter optimization techniques like Design of Experiment (DOE), Taguchi Robust Design method, Failure Mode and Effects Analysis (FMEA), Design for X, Multi-Level Hierarchical Design methodology, and Response Surface methodology
- Covers contemporary and emerging design methods, including Axiomatic Design Principles, Theory of Inventive Problem Solving (TRIZ), and Tolerance Design
- Provides a detailed, step-by-step implementation process for each DFSS tool included
- Covers the structural, organizational, and technical deployment of DFSS within the medical device industry
- Includes a DFSS case study describing the development of a new device
- Presents a global prospective of medical device regulations

Providing both a road map and a toolbox, this is a hands-on reference for medical device product development practitioners, product/service development engineers and architects, DFSS and Six Sigma trainees and trainers, middle management, engineering team leaders, quality engineers and quality consultants, and graduate students in biomedical engineering.

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Editorial Review

Review
"The book is well-written and the authors use well versed descriptions, easy to read figures and tables, and industry-related examples and case studies to explain what can be very complex concepts and processes. This book would be a valuable resource for anyone in the field of medical device design." (*Doody's Book Reviews*, October 2008)

From the Back Cover
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About the Author
Basem S. El-Haik, PhD, is the CEO and President of Six Sigma Professionals, Inc. (www.sixsigmapi.com) in Canton, Michigan, and the author of many bestselling books on Design for Six Sigma. Dr. El-Haik is well known in the DFSS domain and has been a featured speaker at many technical conferences. He has seventeen years of experience in contemporary design and quality engineering methods and has trained, certified, coached, and monitored over 600 belts (Green Belts, Black Belts, and Master Belts) in DFSS and Six Sigma in both tracks: product and service (transactional). basem.haik@sixsigmapi.com

Khalid S. Mekki is a Quality Manager at Baxter Healthcare Corporation, where he has served in various capacities since 2001. He is working toward his PhD in industrial engineering at the University of Illinois at Chicago. Khalid holds a master's degree in mechanical/quality engineering and a bachelor's degree in

mechanical engineering. He has led and completed numerous Design for Six Sigma projects.

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